DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M3298M

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-17

December 23, 1999

Rick Ferreira, CEO
Alliance Medical Corporation
3853 E. Weir Avenue
Phoenix, Arizona 85040

Dear Mr. Ferreira:

We are writing to you because on November 17-19, 1999 FDA Investigator R. Kevin Vogel inspected your facility at 254 West Keene Road, Apopka, Florida, and collected information that revealed serious regulatory problems involving your firm's reprocessing of medical devices.

Under the Federal Food, Drug, and Cosmetic Act (the Act), the products that your firm reprocesses are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers, including reprocessors, conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that devices that you sort and clean for further reprocessing are adulterated within the meaning of section **501(h)** of the Act, because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation does not conform with the QS regulation. These violations include, but are not limited to the following:

QS Regulation/GMPs

1. Failure to establish and implement a quality policy as required by 21 CFR 820.20. For example, personnel on site had no knowledge that such a policy existed (FDA 483, Item, # 4).

2. Failure to establish and maintain procedures to ensure that device history records are maintained to demonstrate that devices are manufactured in accordance with the device master record as required by 21 CFR 820.184. For example, SOP 003, Appendix A, Initial Cleaning Instructions Rejection List states that used Arthrowands should not be reprocessed. However, on November 13, 1999, three Arthrowands were accepted and forwarded for reprocessing (FDA 483, Item #s 2 & 3).

3. Failure to establish and maintain procedures for implementing corrective and preventive action [21 CFR 820.100], including failure to implement and record changes in methods and procedures needed to correct and prevent identified problems [21 CFR 820.100(a)(5)]. For example, there are no procedures to address change control and corrective and preventive actions (FDA 483, Item #5).

4. Failure to monitor production and process controls to ensure that inspection, measuring, and test equipment is suitable and capable of performing its intended purpose [21 CFR 820.72(a)]. For example, there are no procedures to address the calibration of thermometers and pH meters (FDA 483, Item #5).

5. Failure to adequately train personnel to perform their assigned responsibilities as required by 21 CFR 820.25. For example, employees failed to demonstrate a working knowledge of SOPs and/or other processing instructions (FDA 483, Item #1).

6. Failure to document cleaning and maintenance of the facility and process equipment, as required by 21 CFR 820.70(f) and (g). For example, there is no record to document that the processing room and equipment are cleaned or maintained to ensure that adverse effects on product quality are minimized and that personnel protections are in place (FDA 483, Item #6).

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the awards of contracts. FDA has also notified the Occupational Safety and Health Administration (OSHA) of our findings during the inspection of your facility.

We acknowledge receipt of your firm's response dated December 4, 1999, to the Inspectional Observations (FDA 483) and will evaluate the adequacy of the promised corrections during the next inspection of your facility.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Any future responses should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Douglas D. Tolen
Director, Florida District